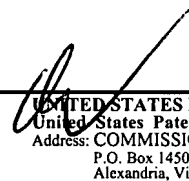




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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,040 | 09/27/2005 | Philippe Sansonetti | 03715.0151 | 4657 |
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22852 7590 10/12/2007
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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| EXAMINER |
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HARLE, JENNIFER I

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| ART UNIT | PAPER NUMBER |
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1654

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| MAIL DATE | DELIVERY MODE |
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10/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/551,040 | Applicant(s) SANSONETTI ET AL. | |
| | Examiner Jennifer I. Harle | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-34 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a method for modulating NOD1 activity comprising expressing NOD1 and contacting with a molecule related to MTP.

Group II, claim(s) 6-8, drawn to a method for modulating inflammation and/or apoptosis comprising administering a molecule related to MTP.

Group III, claim(s) 9-14, 17, and 25, drawn to a molecule related to MTP and compositions thereof.

Group IV, claim(s) 15, drawn to a method for enhancing the immune response of a host comprising administering an antigen and a compound from Group III.

Group V, claim(s) 16 and 19, drawn to method for providing an immune response in a host in a host comprising administering a composition from Group III.

Group VI, claim(s) 18, drawn to method of vaccination comprising administering a composition from Group III.

Group VII, claim(s) 20, drawn to a method for detecting the dysfunction of a molecule of the inflammatory and/or apoptosis pathway in which Nod1 is involved including use of MPT or agonist thereof.

Group VIII, claim(s) 21, drawn to method for screening a molecule, which is capable of modulating an inflammatory and/or apoptotic response obtained after direct or indirect interaction between Nod1 and MPT.

Group IX, claim(s) 22, drawn to a molecule identified by the screening process of claim 21, would include a molecule related to MTP.

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Group X, claim(s) 23, drawn to method for modulation of inflammation and/or apoptosis comprising administering a molecule identified by the screening process of Group VIII.

Group XI, claim(s) 24, drawn to a complex of Nod1 and MTP.

Group XII, claim(s) 26-29, drawn to method for detecting peptidoglycan, includes MTP.

Group XIII, claim(s) 30-33, drawn to method for the detection of peptidoglycan in a sample and optionally determining the Gram-negative or Gram-positive bacterial origin of said peptidoglycan, includes MTP.

Group XIV, claim(s) 34, drawn to method for screening for a molecule that modulates interaction between Gram-negative bacteria peptidoglycan and Nod1 comprising contacting with Nod1.

2. The inventions listed as Groups I-VII and IX-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they contain muramyl tripeptide, which peptide is known. See Uehara, et al. (2003) J. Bacteriol. 185, 679-682 (see Abstract) (provided by Applicant). Therefore the muramyl tripeptide can not be considered as the single general inventive concept. Moreover, the relation of Nod1 and inflammation or apoptosis via NF-kappaB or IL-8 (Group VIII) is known from US 2002/0197693 [0009] and [0260] (provided by Applicant).

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

MTP

Specific molecules related to MTP

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L-Ala-D-Glu-mesoDAP

Specific L-Ala-D-Glu-mesoDAP biological derivatives

Specific L-Ala-D-Glu-mesoDAP peptidomimetics

Applicant is required, in reply to this action, to elect a single species, i.e. a specific compound identifying all constituents – L-Ala-D-Glu-mesoDAP, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claims 26-34 relate to MTP only.

All other claims are generic.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: MTP is known as set forth above and the derivatives/peptidomimetics or related peptides will not necessarily contain any common core, i.e. are not so linked as to form a single general inventive concept.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

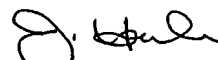
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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jennifer I. Harle
Examiner
Art Unit 1654

October 9, 2007